



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/284,297	07/05/2000	Dosuk D. Lee	04712/02000G	2121

7590

01/17/2003

Mary Rose Scozzafava, Esq.
Hale and Dorr LLP
60 State Street
Boston, MA 02109

[REDACTED] EXAMINER

LEVY, NEIL S

[REDACTED] ART UNIT

[REDACTED] PAPER NUMBER

1616

DATE MAILED: 01/17/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

284297

Applicant(s)

Lee et al

Examiner

NOL Cuy

Group-Art Unit

162

23

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication .
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

Responsive to communication(s) filed on 8/6/02.

This action is FINAL.

Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 1 1; 453 O.G. 213.

Disposition of Claims

Claim(s) 40,92431/0311-151 is/are pending in the application.

Of the above claim(s) _____ is/are withdrawn from consideration.

Claim(s) _____ is/are allowed.

Claim(s) 494343/03,111-151 is/are rejected.

Claim(s) _____ is/are objected to.

Claim(s) _____ are subject to restriction or election requirement.

Application Papers

See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

The proposed drawing correction, filed on _____ is approved disapproved.

The drawing(s) filed on _____ is/are objected to by the Examiner.

The specification is objected to by the Examiner.

The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

All Some* None of the CERTIFIED copies of the priority documents have been received.

received in Application No. (Series Code/Serial Number) _____.

received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

Attachment(s)

Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

Interview Summary, PTO-413

Notice of Reference(s) Cited, PTO-892

Notice of Informal Patent Application, PTO-152

Notice of Draftsperson's Patent Drawing Review, PTO-948

Other _____

Office Action Summary

Art Unit: 1614

Receipt is acknowledged of change of address, Petition and amendment (8/6/02). Please provide an abstract; none is evident.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Applicants arguments of 8/6/02 in response to examiner's 112 rejections, in essence were that the specification limits and defines the terms. With, amendments these arguments are persuasive, and, as applicant request non-elected species to be examined if elected claims are found free of the prior art, the now-amended non-elected claims would at least be free of 112 issues. The species requirement is withdrawn. The 112 rejections are withdrawn.

Claims 40, 42, 43, 103, 111-118, 120, 121, 127-131, 133-135, 138-146 are rejected under 35 U.S.C. 102(e) as being anticipated by Constantz et al 5962028.

The rejection of record is maintained based on parent, as applicant has now claimed an earlier date. Apatite with carbonate (col. 2, lines 35-54) provides for a bone substitute, a poorly crystalline appetite Ca/P (Col. 4, last paragraph) Calcium carbonate) the instant promoter (claim 118) is mixed with tetra Calcium phosphate (col. 8, line 4-10). F can be added to provide a selected characteristic (lines 24-27, col. 8, lines 63-65, col. 5) such as dental application. Thus, F, in contact with the Strongly (col. 6, lines 60, 61) bioresorbable implant (col. 3, last paragraph) is a biocompatible material as of instant claim 42. Compressed Materials with high compressive strength (claim 3) can be formed by mixing dry ingredients (col. 6, top) and pressing (rolling), then hydrating (paragraph 2, col. 6). The instant claim 40 predetermined shapes is met by Constantz

Art Unit: 1614

paste; the shape predetermined by the cavity into which it is molded, for example (col. 7, lines 27-34) or as implants or other objects (lines 38-47, col. 7). Here, The clay-like mix applied as implant in a bone site also meets instant claim 103, and 138. Example 1 prepares a bioceramic utilizing an endo thermic reaction, as required of instant claim 111, and 112. Hydration fluids are at col. 6, lines 10-14; water. Lyophilization (claim 115) is at col. 9, top; in vivo setting at col. 7, last paragraph (claim 113) as are biological agents (claim 116) and claim 117 growth factory antibiotics (col. 7, top), also supplemental material (claim 20); and so on. Demineralized bone (claim 21) can be met by the Collagen of Col. 6, lines 66, 67.

Claims 40, 42, 43, 103, 111-118, 120-123, 125, 127-131, 133-147, 149-151 are rejected under 35 U.S.C. 103(a) as being unpatentable over Constantz - 5962028.

The instant invention as it is claimed is shown by Constantz; See above, but for a few specific characteristics. These are obvious functions of the mix of ingredients and normal modes of preparation and use; Constantz reports bone replacement, thus the same X ray pattern would ensue (col. 5, top) as of instant claim 136. So would the density and compression as the Constantz products are of the density and compression (col. 10) as would result from use of the equipment, presses, disclosed at col. 8, line 38-43). As far as the criteria for resorption within a year, the test would be difficult to perform; how would one know when 80 or 90% resorption had occurred, and when – unless X-ray bone scans were done and redone; and animal's sacrificed, at one year? However, the instant methods and compositions are applied, so the results would obviously follow-90% resorption if inserted in a rat, by one year. Column 7 recites a

Art Unit: 1614

variety of objects and formed products, flowable or formable (lines 38-48), 60-63, col. 7). Although no specific structural geometry is identified, the fact that dry ingredients are combined and mixed (col. 8, lines 3-21) speaks for at least a powder or shaped form, of Apatitic CaP; the instant claim 43 compositions. See also col. 9, line 5-free flowing mixes.

Claims 40, 42, 43, 103, 111-120, 126-134, 138-145 and 148 are rejected under 35 U.S.C. 102(e) as being anticipated by Brown et al 6201039.

For claim 42; See example 1: CaP and the instant (claim 118) Promoter, (although the word promoter is not used), Ca Carbonate, are mixed powder, resulting in a formed product – 2- 5 micron powder (line 37-49, col. 13). Collagen (col. 14) the “dematerialized bone”, as examiner sees the term is placed in contact with the product. Compression is seen as a result of blending mixing. The instant claims do not require any particular force applied to achieve a compressed form. The resultant product (Example 5) with distilled water preparation, when placed in rats resorbed in 12 weeks. Added antibiotic is at example 7A. Pellets are formed in Example 13. Addition of CaP to a promoter, a second calcium source, and pressing, (claim 40) is seen as accomplished by the mixing; added water is not seen as required after formation of an: object; the Brown Product however, as the mixed product of Ca Carbonate and Ca Phosphate, is in fact the same as the instant object. Further shaping, setting and formation into pellets or implantable forms of the shape of the bone to be repaired is shown by Brown – Examples 12, 13.

Claims 40, 42, 43, 103, 111-151 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brown or Constantz in view of Fukase et al '90 and Tung 5037639.

Brown or Constantz (above) provide the essence of the instant invention as it claimed, with Language open to interpretation as seen in Brown and Const only regarding non identified or quantified features, such as strongly bio restorable, compressed objects, selected characteristics, pressed powder and steps within the comprising guise not requiring sequential hydration, absent any showing of criticality in any of these respects. However, amorphous character, although not quantified by applicant, and DCPD, were not evident. Fukase shows setting times adjustable with DCPD (P. 1856). Tung shows ACP has enhanced solubility and conversion to apatitic (col. 2, summary).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made desiring to utilize Brown or Constantz to prepare, provide and implant bone replacement poorly crystalline hydroxy apatitic compositions in order to repair bone and teeth defects, but with the added advantage of fast setting with DCPD, and enhanced solubility and resorption, with amorphous CaP.

It has not clearly been established by objective showing of some unobvious and/or unexpected results that the administration of the particular form of active, the particular preparation or treatment provides any greater level of prior art expectation as claimed. Further, no criticality as to the ingredient concentrations, ratios or Application has been shown by applicant.

Art Unit: 1614

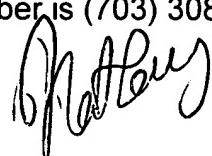
The selection of each ingredient and form thereof is a result effective parameter chosen to obtain the desired effects. It would be obvious to vary the nature of each ingredients to optimize the effects desired, and the use ingredients for the functionality for which they are known to be used is not a basis for patentability.

Applicant's arguments filed 8/16/02 have been fully considered but they are not persuasive. Applicant's arguments have been addressed above, or considered in the rejections presented. Withdrawn rejections, in accord with applicants' arguments and amendments have been replaced however, as even though more clearly presented, the claimed invention is not seen as outside of the prior art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Neil Levy whose telephone number is (703)308-2412. The examiner can normally be reached on Tuesday through Friday 7 AM to 5:30 Pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jose Dees can be reached on (703) 308-4628. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.



Levy/LR
January 15, 2003

NEIL S. LEVY
PRIMARY EXAMINER